certified limits, including how the certified limits were arrived at (e.g., sample analysis, quantitative estimate based on production process), and its accuracy and precision. This will be particularly useful if the range of the certified limit for an active or inert ingredient is greater than the standard certified limits.

(d) *Special cases.* If the Agency finds unacceptable any certified limit (either standard, or applicant proposed), the Agency will inform the registrant or applicant of its determination and will provide supporting reasons. The Agency may also recommend alternative limits to the applicant. The Agency may require, on a case-by-case basis, any or all of the following:

(1) More precise limits.

(2) More thorough explanation of how the certified limits were determined.

(3) A narrower range between the upper and lower certified limits than that proposed.

(e) *Certification statement.* The applicant must certify the accuracy of the information presented, and that the certified limits of the ingredients will be maintained. The following statement, signed by the authorized representative of the company, is acceptable:

I hereby certify that, for purposes of FIFRA sec. 12(a)(1)(C), the description of the composition of [*insert product name*], EPA Reg. No. [*insert registration number*], refers to the composition set forth on the Statement of Formula and supporting materials. This description includes the representations that: (1) no ingredient will be present in the product in an amount greater than the upper certified limit or in an amount less than the lower certified limit (if required) specified for that ingredient in a currently approved Statement of Formula (or as calculated by the Agency); and (2) if the Agency requires that the source of supply of an ingredient be specified, that all quantities of such ingredient will be obtained from the source specified in the Statement of Formula.

§ 158.355 Enforcement analytical method.

An analytical method suitable for enforcement purposes must be provided for each active ingredient in the product and for each other ingredient or impurity that the Agency determines to be toxicologically significant.

Subpart E—Product Performance

§ 158.400 Product performance data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use this table to determine the product performance data requirements for a particular pesticide product. Notes that apply to an individual test, including specific conditions, qualifications, or exceptions to the designated test are listed in paragraph (e) of this section.

(b) *Use patterns.* The terrestrial use pattern includes products classified under the general use patterns of terrestrial food crop and terrestrial nonfood crop. The aquatic use pattern includes products classified under the general use patterns of aquatic food crop and aquatic nonfood. The greenhouse use pattern includes products classified under the general use patterns of greenhouse food crop and greenhouse nonfood crop. Data are also required for the general use patterns of forestry use, residential outdoor use, and indoor use, which includes both food and nonfood uses.

(c) *Key.* CR=Conditionally required; NR=Not required; R=Required; EP=End-use product; MP=Manufacturing-use product; TEP=Typical end-use product.

(d) *Table.* The following table lists the data requirements that pertain to product performance. The table notes are shown in paragraph (e) of this section.

TABLE—PRODUCT PERFORMANCE DATA REQUIREMENTS

Guideline Number	Data Requirement	Use Pattern									Test substance to support		Test Note No.
		Terrestrial		Aquatic		Greenhouse		Forestry	Residential Outdoor	Indoor	MP	EP	
		Food Crop	Nonfood Crop	Food	Nonfood	Food Crop	Nonfood Crop						
810.2700	Products with prion-related claims	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1
Efficacy of fungicides and nematicides													
93–16	Products for control of organisms producing mycotoxins	CR	NR	CR	NR	CR	NR	NR	NR	NR	NR	EP	1
Efficacy of vertebrate control agents													
96–5	Avian toxicants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
96–6	Avian repellents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–7	Avian frightening agents	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
96–9	Bat toxicants and repellents	NR	NR	NR	NR	NR	NR	NR	NR	R	NR	EP	1
96–10	Commensal rodenticides	R	R	NR	NR	NR	NR	NR	R	R	TEP	EP	1
96–12	Rodenticides on farm and rangelands	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1
95–13	Rodent fumigants	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–16	Rodent reproductive inhibitors	R	R	NR	NR	NR	NR	NR	R	R	NR	EP	1
95–17	Mammalian predacides	R	R	NR	NR	NR	NR	NR	R	NR	NR	EP	1

(e) *Test notes.* The following notes appy to the data requirements table in paragraph (d) of this section.

1. The Agency has waived the requirement to submit product performance data unless the pesticide product bears a claim to control pest microorganisms that pose a threat to human health and whose presence cannot readily be observed by the user including, but not limited to, microorganisms infectious to man in any area of the inanimate environment, or a claim to control vertebrates (such as rodents, birds, bats, canids, and skunks) that may directly or indirectly transmit diseases to humans. However each registrant must ensure through testing that his product is efficacious when used in accordance with label directions and commonly accepted pest control practices. The Agency reserves the right to require, on a case-by-case basis, submission of product performance data for any pesticide product registered or proposed for registration.

2. [Reserved]

[72 FR 60957, Oct. 26, 2007, as amended at 78 FR 13507, Feb. 28, 2013; 78 FR 26978, May 8, 2013]

Subpart F—Toxicology

§ 158.500 Toxicology data requirements table.

(a) *General.* Sections 158.100 through 158.130 describe how to use the data table in paragraph (d) of this section to determine the toxicology data requirements for a particular pesticide product. Notes that apply to an individual test and include specific conditions, qualifications, or exceptions to the designated test in the table are listed in paragraph (e) of this section.

(b) *Use patterns.* (1) Food use patterns include products classified under the general use patterns of terrestrial food crop use, terrestrial feed crop use, aquatic food crop use, greenhouse food crop use, and indoor food use.

(2) Nonfood use patterns include products classified under the general use patterns of terrestrial nonfood crop use, aquatic nonfood use, greenhouse nonfood crop use, forestry use, residential outdoor use, and indoor nonfood use.

(c) *Key.* R=Required; CR=Conditionally required; NR=Not required; MP=Manufacturing-use product; EP=End-use product; TGAI=Technical grade of the active ingredient; PAI=Pure active ingredient; PAIRA=Pure active ingredient radiolabeled; Choice=Choice of several test substances depending on study required.

(d) *Table.* The following table lists the toxicology data requirements. The table notes are shown in paragraph (e) of this section.

TABLE—TOXICOLOGY DATA REQUIREMENTS

Guideline Number	Data Requirements	Use Pattern		Test substance to support		Test Note No.
		Food	Nonfood	MP	EP	
Acute Testing						
870.1100	Acute oral toxicity - rat	R	R	TGAI and MP	TGAI, EP, and possibly diluted EP	1, 2
870.1200	Acute dermal toxicity	R	R	TGAI and MP	TGAI, EP	1, 2, 3
870.1300	Acute inhalation toxicity - rat	R	R	TGAI and MP	TGAI and EP	4
870.2400	Primary eye irritation - rabbit	R	R	TGAI and MP	TGAI and EP	3
870.2500	Primary dermal irritation	R	R	TGAI and MP	TGAI and EP	1, 3
870.2600	Dermal sensitization	R	R	TGAI and MP	TGAI and EP	3, 5
870.6100	Delayed neurotoxicity (acute) - hen	CR	CR	TGAI	TGAI	6